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10/565,830	01/25/2006	Isao Karube	P29193	7937

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EXAMINER	
KASTEN, ROBERT J	

ART UNIT	PAPER NUMBER
1795	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/565,830	KARUBE ET AL.	
	Examiner	Art Unit	
	ROBERT KASTEN	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) *42-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41 and 57-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :04/25/2006, 05/24/2006 and 05/21/2008.

DETAILED ACTION

This is the first non-final action on the merits.

Claims 1-59 were subject to a requirement for restriction. Applicant has elected Group I, drawn to claims 1-41 and 57-59, which are pending in this application, with traverse. Claims 42-56 have been withdrawn.

Claims 7-10, 12-13, 15, 18-20, 23-25, 29, 31, 33-35, 38, 40 and 57-58 have been amended. No new matter has been added.

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on 07/10/2009 is acknowledged. The traversal is on the ground(s) that the office has failed to set forth how DAVIES et al. becomes a basis for Restriction Requirement. This is not found persuasive while it is true that different categories of invention may not necessarily lack unity of invention as required in an international or national stage application, the different categories of invention must be able to provide a special technical feature common to both. In the case that the special technical feature of both categories of invention does not avoid the prior art, a requirement for restriction may be made between the two categories of invention. In the present case, the prior art document DAVIES has been shown to teach a biosensor formed through the folding of substrate to internalize electrodes (see Requirement for Restriction/Election, 06/10/2009). The Office therefore concluded that the claimed inventions lack a

corresponding special technical feature, and that a Requirement for Restriction was proper in this case.

The requirement is still deemed proper and is therefore made FINAL.

Specification

2. The use of the trademark BLUETOOTH has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 40 contains the trademark/trade name Bluetooth. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not

identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe either a wireless protocol used in the wireless unit or structural characteristics of the wireless unit itself and, accordingly, the identification/description is indefinite.

Claim Objections

4. Claims 18-19, 21, 23 and 27 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims are drawn to product-by-process language only and do not teach positively limiting structural features to the parent claims. .

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-2, 4-5, 7-10, 13, 15, 18-19, 23-25, 29-32, 38 and 57-58 are rejected under 35 U.S.C. 102(e) as being anticipated by DAVIES et al. (US 2003/0217918), from here on referred to as DAVIES.

Claims 1, 18-19, 21, 23, 27 and 57-58 is/are considered product-by-process claims. The cited prior art teaches all of the positively recited structure of the claimed apparatus or product. The determination of patentability is based upon the apparatus structure itself. The patentability of a product or apparatus does not depend on its method of production or formation. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (see MPEP § 2113).

Concerning Claim 1, DAVIES teaches a glucose sensor (title). This glucose sensor is inherently a biosensor. The biosensor is best exemplified by Figure 5a and described in [0030]. The biosensor contains a substrate 70 with an insulating layer 74, thus forming an (electrically) insulating substrate. Because this is an apparatus claim, the means of production is not limiting and the prior art structure anticipates the claim by simply reciting all structural characteristics.

Concerning Claim 2, DAVIES teaches I glucose sensor (title) best exemplified by Figures 5a-b and [0030]. Specifically, DAVIES teaches an apparatus comprising the following characteristics:

- Electrodes (conductive tracks) 71 and 72 disposed in a space (Fig. 9C, 110) in a folded substrate 70, such that substrate 70 forms a base and a cover around said electrodes (Fig. 5b and [0030])
- A sample inlet space (Fig. 9C), created by spacers 24 and 25 (as shown in Fig. 3 and [0029])
- A sample cavity (transfer path) 27 (Fig. 3, [0029])
- The electrodes 71 and 72 being disposed on the substrate 70 which also comprises an insulating layer 74, thus forming an (electrically) insulating substrate [0030]
- Spacers 24 and 25 can also be adhesive pads (an adhesive layer) 101 and 102 (Fig. 9C, [0028])

Because this is an apparatus claim, the means of production is not limiting and the prior art structure anticipates the claim by simply reciting all structural characteristics.

Concerning Claim 4, DAVIES teaches a biosensor of Figure 5B in [0030] with the following features:

- A sensor body made by substrate 70, folded into a square-columnar (cylindrical) structure, said substrate endowed with an insulating layer 74 [0030]
- Electrodes 71 and 72 disposed on the inside of the sensor body [0030]
- A sensor inlet portion (Fig. 9C, 110)
- A sample cavity (transfer path) 27 (Fig. 3, [0029])

Concerning Claim 5, DAVIES shows in Figure 5B that the sensor can be of a square-columnar shape.

Concerning Claim 7-8, DAVIES teaches that a reagent layer is disposed on both the sample-receiving chamber and the working electrode (abstract).

Concerning Claim 9, DAVIES teaches a biosensor in Figure 5B where the sample inlet portion (not numbered) is clearly shown to be a one end of the sensor.

Concerning Claim 10, DAVIES teaches that a hydrophilic film is placed on the adhesive pads 101-103 of Figures 9A-C. These pads are around the surface of the sample transfer path as shown in Figure 9C. The hydrophilic film is treated with surfactant [0028].

Concerning Claim 13, DAVIES teaches that the substrate 70 in Figure 5B can be made from a plastic film (polyester film) [0031].

Concerning Claim 15, DAVIES teaches that the electrodes can be made of carbon, gold, etc. [0031].

Concerning Claim 18, DAVIES teaches all the limitations of claim 2. The claim language is product-by-process and absent evidence to the contrary is not limiting.

Concerning Claim 19, DAVIES teaches all the limitations of claim 2. The claim language is product-by-process and absent evidence to the contrary is not limiting.

Concerning Claim 23, DAVIES teaches all the limitations of claim 2. The claim language is product-by-process and absent evidence to the contrary is not limiting.

Concerning Claim 24, DAVIES teaches that the reagent layer can be disposed over the working electrode [0033]. Absent evidence to the contrary, the product-by-process claim language is considered non-limiting.

Concerning Claim 25, DAVIES teaches that there may be multiple reagent layers (a plurality of sub-layers), and that layers may contain different reagents (some containing enzyme, some containing mediator) [0033].

Concerning Claim 29, DAVIES teaches that one of the reagent layers may be an enzyme [0033].

Concerning Claim 30, DAVIES teaches that if an enzyme is used as one of the regent layers, the enzyme could be glucose oxidase [0033].

Concerning Claim 31, DAVIES teaches that a reagent layer may contain both the enzyme and the mediator [0033].

Concerning Claim 32, DAVIES teaches that the mediator may be ferrocene [0033].

Concerning Claims 38, DAVIES teaches all the limitations of claim 1. Further, DAVIES teaches a biosensor with the following features:

- A measuring unit (implied from associated meters for taking measurements) [0022]
- A display unit [0042]
- A memory unit (implied by a recall function of recalling stored results) [0042]

Further, the Courts have held that if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The Courts have held that it is well settled that the recitation of a new intended use, for an old product, does not make a claim to that old product patentable. See *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) (see MPEP § 2114). Therefore, the recitations of intended use in the claim language are not limiting.

Concerning Claim 39, DAVIES teaches all the limitations of claim 38. Further, the Courts have held that if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The Courts have held that it is well settled that the recitation of a new intended use, for an old product, does not make a claim to that old product patentable. See *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) (see MPEP § 2114). Therefore, the recitations of intended use in the claim language are not limiting.

Concerning Claim 57, DAVIES teaches a glucose sensor (title) best exemplified by Figures 5a-b and [0030]. Specifically, DAVIES teaches an apparatus comprising the following characteristics:

- Electrodes (conductive tracks) 71 and 72 disposed in a space (Fig. 9C, 110) in a folded substrate 70, such that substrate 70 forms a base and a cover around said electrodes (Fig. 5b and [0030])

- A sample inlet space (Fig. 9C, 110), created by spacers 24 and 25 (as shown in Fig. 3 and [0029])
- A sample cavity (transfer path) 27 (Fig. 3, [0029])
- The electrodes 71 and 72 being disposed on the substrate 70 which also comprises an insulating layer 74, thus forming an (electrically) insulating substrate [0030]
- Spacers 24 and 25 can also be adhesive pads (an adhesive layer) 101 and 102 (Fig. 9C, [0028])

Because this is an apparatus claim, the means of production is not limiting and the prior art structure anticipates the claim by simply reciting all structural characteristics. Further, as can be seen in Figure 9B, a portion of the biosensor is cut along a certain line as a final step in biosensor creation [0028]. This prior art teaching of cutting anticipates the claimed invention. The method of forming the biosensor does not further structurally limit the claim.

Concerning Claim 58, DAVIES teaches a glucose sensor (title) best exemplified by Figures 5a-b and [0030]. Specifically, DAVIES teaches an apparatus comprising the following characteristics:

- Electrodes (conductive tracks) 71 and 72 disposed in a space (Fig. 9C, 110) in a folded substrate 70, such that substrate 70 forms a base and a cover around said electrodes (Fig. 5b and [0030])
- A sample inlet space (Fig. 9C, 110), inherent created by spacers 24 and 25 (as shown in Fig. 3 and [0029])

- A sample cavity (transfer path) 27 (Fig. 3, [0029])
- The electrodes 71 and 72 being disposed on the substrate 70 which also comprises an insulating layer 74, thus forming an (electrically) insulating substrate [0030]
- Spacers 24 and 25 can also be adhesive pads (an adhesive layer) 101 and 102 (Fig. 9C, [0028])

Because this is an apparatus claim, the means of production is not limiting and the prior art structure anticipates the claim by simply reciting all structural characteristics. Further, DAVIES teaches the use of pressure sensitive adhesive, which is implied as the means to secure the folded biosensor in a closed conformation. Therefore, DAVIES implicitly teaches that the device is subjected to a compression fixing step, and therefore inherently contains all the structural features endowed to the device as a consequence of said fixing step.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 3, 20 and 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over DAVIES.

Concerning Claim 3, DAVIES teaches a biosensor with all the limitations of claim 2, said biosensor being constructed by folding of the substrate back on itself, thus internalizing the electrodes printed on it (see Fig. 5A).

DAVIES does not expressly teach that the substrate contain perforations to aid in this folding.

At the time of the invention, it would have been *prima facie* obvious to provide the implied folding region of DAVIES with a series of perforations. Perforations are a well established method in many different arts of helping in the folding of articles, so employing this technique in the biosensor art would likely be successful. One would be

motivated to use perforations instead of simply bending the substrate like in DAVIES because perforations could help guide the fold during the production of the biosensor, helping to keep the alignment of the electrodes consistent and ensuring consistent quality should the sensors ever be mass produced.

Concerning Claim 20, DAVIES teaches all the limitations of claim 2.

DAVIES does not expressly teach that the reagent is included in the adhesive layer. The use of a one-piece, integrated construction instead of the structure disclosed or taught in the prior art would have been within the ambit of a person of ordinary skill in the art. See *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965) (see MPEP § 2144.04). In the present case, DAVIES positively teaches each of a reagent and an adhesive layer, but as separate articles disposed proximate the sample receiving chamber. One of ordinary skill in the art would have been able to reason that, if sought, the reagent and any other surface could be combined, even the adhesive layer. Therefore, at the time of the invention, it would have been *prima facie* obvious to one of ordinary skill in the art to combine the reagent and the adhesive layer.

Concerning Claim 22, DAVIES teaches all the limitations of claim 7.

DAVIES does not expressly teach that the reagent is formed after purification.

The use of an unpurified reagent layer has many disadvantages. Unpurified reagents will likely contain contaminants, which could lead to regions of the reagent layer being less responsive than other regions. For the sake of uniform reagent activity, one would wish to avoid this impure condition. Further, these contaminants could lead to false positives, as secondary reagents could lead to detection of non-target analytes

in a sample, though to the user the readings will appear to confirm the presence of target analyte. Finally, unpurified reagent could cause uneven exhaustion of the biosensor, as regions with higher concentrations of reagent last longer than those with lower concentrations. Such spatial dependence on target analyte tests would most likely lead to skewed results, such as some analyte going undetected by what should be an otherwise perfectly functional biosensor.

11. Claims 6, 14 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over DAVIES in view of FUJIWARA et al. (US 6,004,441), from here on referred to as FUJIWARA.

Concerning Claim 6, DAVIES teaches a biosensor with all the limitations of claim 2.

DAVIES does not expressly teach that the electrode be defined by a resist layer.

However, FUJIWARA teaches that in the conventional biosensor, a resist layer is often employed on the electrode (col. 1, lines 39-45).

The advantage of adding a resist layer to a working electrode is limiting the effective area the electrode (col. 1, lines 39-45). The motivation for limiting the effective area of the electrode would be to control the overall conductance of the electrode, whereby the user would be able to control the voltage readings from the device so as to better tune the device to the concentration of sample likely to be observed (for instance, with higher concentrations of analyte likely to be detected, a higher conductance and therefore lower voltage would be advantageous so as to reduce the stress of constant

high-voltage readings to the measurement unit.) Therefore, at the time of the invention, it would have been *prima facie* obvious to one of ordinary skill in the art to use a resist layer to help define the electrode area in the device of DAVIES.

Concerning Claim 14, DAVIES teaches all the limitations of claim 13. Further, DAVIES teaches that the substrate may be made of a polyester film [0031].

DAVIES does not expressly teach that substrate be made of polyethylene terephthalate, which is a specific polyester.

However, FUJIWARA teaches a biosensor comprising an insulating substrate, said substrate being comprised of polyethylene terephthalate (PET) (col. 2, lines 40-42).

The prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). In the present case, the prior art has already been shown to teach that a polyester substrate can be used in an operable biosensor such as the one taught by DAVIES. Given this teaching, and the knowledge that PET is a polyester, if PET had been shown to function as a substrate in other biosensor devices, one of ordinary skill in the art would certainly expect that if the polyester of DAVIES were PET, the device as taught would still function properly. Additionally, FUJIWARA teaches that PET acts as an insulating substrate (col. 2, lines 40-42), which is advantageous in a biosensor apparatus such as DAVIES because the insulating substrate would not interfere with the flow of electrons through the conductive regions of the substrate. Therefore, at the time of the invention,

it would have been *prima facie* obvious to those of ordinary skill in the art to use PET as the polyester film substrate in DAVIES.

Concerning Claim 21, the claim recites strictly product by process language, and absent evidence to the contrary is not further structurally limiting.

12. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over DAVIES in view of VADGAMA et al. (US 4,919,767), from here on referred to as VADGAMA.

Concerning Claim 11, DAVIES teaches all the limitations of claim 10.

DAVIES does not expressly teach that a lipid be applied around the sample inlet port, nor that the lipid be lecithin.

However, VADGAMA teaches a sensor for analyte determination (title), specifically a sensor which comprises a membrane (claim 6) positioned between the sample and electrodes, said membrane comprising pores partially filled with a liquid (claim 6). This liquid can comprise a lipid (claim 7), wherein the lipid can be lecithin (claim 8).

The motivation for using a lecithin in a biosensor, such as in a membrane like in VADGAMA, is that the lipid has been shown to screen interfering species from permeating through to the electrodes, the advantage being that false positives or skewed results could be avoided by eliminating these interfering species. Since both VADGAMA (col. 4, lines 31-38) and DAVIES (title) teach that their sensors are used for glucose, one would have expected the membrane could be successfully employed in the device of DAVIES. Therefore, at the time of the invention, it would have been *prima*

facie obvious to those of ordinary skill in the art to provide the lecithin containing membrane of VADGAMA in the sensor of DAVIES to facilitate elimination of interfering species that could skew test results.

13. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over DAVIES in view of YUZHAKOV et al. (US 2003/0143113), from here on referred to as YUZHAKOV.

Concerning Claim 12, DAVIES teaches all the limitations of claim 2.

DAVIES does not expressly teach a curved portion to the biosensor.

However, YUZHAKOV teaches a device for the collection of physiological samples (title) depicted in Figure 5 and described in [0074]. Specifically, the collector contains an aperture 68 which contains a microneedle (not numbered) for collection of a sample from a source such as a patient. The aperture can be considered the sample inlet port of the device, considering that the sample must necessarily pass through this aperture to the microneedle to enter the collector. This aperture clearly has a curved portion.

The motivation for providing a curved portion at the sample injection port of the device is for ease of use by the user. The curved portion would cup the finger and hold it in place, but also help facilitate funneling of the sample into the device if need be. A curved portion could easily be added to the device of DAVIES as it would require little more than some additional substrate be left on the end of the sensor. Therefore, at the time of the invention, it would have been *prima facie* obvious to one of ordinary skill in

the art to provide a curved portion like in YUZHAKOV in the biosensor of DAVIES to improve the ease of use.

14. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over DAVIES in view of HUANG et al. (US 2004/0256228), from here on referred to as HUANG.

Concerning Claim 16, DAVIES teaches all the limitations of claim 15.

DAVIES does not expressly teach that the electrodes can be made out of nickel.

However, HUANG teaches a disposable electrochemical sensor strip (title) in which the electrode may be a pure nickel electrode [0096].

The choice of a specific electrode material is a matter of the intended use of the electrode (HUANG, [0010]). For instance, HUANG teaches that nickel is advantageous for its use as a counter electrode due to its low conductive resistance [0010]. More generally, a lower conductive resistance is likely to be advantageous as it would likely allow the sensor to run at a lower voltage and to generate less heat. A biosensor running which functions at a lower temperature is likely to have a long operational lifetime, as well as be unlikely to cause potential harm to the target analyte if the ability to recover and/or reuse the target analyte is preferred. Therefore, at the time of the invention, it would have been *prima facie* obvious to one of ordinary skill in the art to use a nickel electrode like in HUANG when making a new sensor element such as the device of DAVIES.

15. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over DAVIES in view of WOHLSTADTER et al. (US 6,066,448), from here on referred to as WOHLSTADTER.

Concerning Claim 17, DAVIES teaches all the limitations of claim 15.

DAVIES does not expressly teach what forms of carbon are suitable to be used as an electrode.

However, WOHLSTADTER teaches a device for the detection of target analyte via electrochemiluminescence (claim 1), in which the electrodes can be made of carbon nanotubes (claim 2).

The motivation for using carbon nanotubes is that they have been shown to have suitable conductive properties for use as electrodes (col. 27, lines 21-30). Further, in the present case, there are a finite number of carbon forms, and the teaching that some of these are useful as electrodes in electrochemical sensors would have led one of ordinary skill in the art to try those taught carbon forms in a biosensor such as DAVIES with a reasonable expectation of success. Therefore, at the time of the invention, it would have been *prima facie* to one of ordinary skill in the art to try carbon nanotubes like in WOHLSTADTER in the device of DAVIES in order to facilitate application suitably conductive carbon electrodes in the prior art device of DAVIES.

16. Claim 26-28 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over DAVIES in view of BHULLAR et al. (US 6,413,395), from here on referred to as BHULLAR.

Concerning Claim 26, DAVIES teaches all the limitations of claim 25.

DAVIES does not expressly teach that there be a convex partition between the two different reagent layers.

However, BHULLAR teaches a biosensor apparatus best exemplified by Figure 3 and col. 4, lines 12-63. In particular, BHULLAR teaches a foldable biosensor that when in the folded conformation, provide a plurality of stacks 20, 22, and 25 stacked on top of each other (col. 4, lines 12-14). These plates include convex microstructures 86 (col. 4, line 64) which can be covered with a reagent 100 (col. 6, lines 1-2). Because of this stacked configuration, each reagent layer is separated by a convex microstructure.

The motivation for using these convex microstructures is an ability to help control sample fluid flow inside the biosensor (col. 4, lines 64-67). Control of the sample would enable the user to configure the device such that sample react with different reagents in different orders, and would also facilitate more effective flow of the sample over multiple layers and the potential energy of the fluid may be enough for flow through the various reagent regions. Therefore, at the time of the invention, it would have been *prima facie* obvious to one of ordinary skill in the art to provide the device of DAVIES with convex microstructures like in BHULLAR to facilitate better fluid movement and control.

Concerning Claim 27, absent evidence to the contrary, the product by process language of claim 27 is not further structurally limiting.

Concerning Claim 28, BHULLAR does not expressly teach the composition of the convex partition. One would wish to fashion the convex partition out of a non-reactive substance like carbon so as not to interfere with the sample/reagent reaction or other side reactions important to the detection of the target analyte. Therefore, at the time of the invention, it would have been *prima facie* obvious to one of ordinary skill in the art to fashion the convex partitions of BHULLAR in the device of modified DAVIES out of carbon to ensure the partitions did not interfere with the reagent reactions.

Concerning Claim 37, DAVIES does not expressly teach that the electrodes can be arranged as part of an array.

However, BHULLAR teaches a biosensor device in which multiple assays may be performed using only one sample, since the sample can be separated into different chambers with different reagents and electrode sets (col. 10, lines 21-35). This necessarily teaches that there be an array of electrodes.

One would be motivated to provide an array of electrodes like in BHULLAR because of the aforementioned ability to use one sample in multiple, separate reagent reactions and detections. Detecting one sample simultaneously across multiple electrodes would allow for fewer sample collections as the amount of information learned from each individual sample would increase. Therefore, at the time of the invention, it would have been *prima facie* obvious to one of ordinary skill in the art to provide the DAVIES in an array like in BHULLAR to allow for simultaneous detection of a single sample with different reagents.

17. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over DAVIES in view of MAO et al. (US 2004/0099529), from here on referred to as MAO, and further in view of SAY et al. (US 2005/0199494), from here on referred to as SAY.

Concerning Claim 33, DAVIES teaches all the limitations of claim 7.

DAVIES does not expressly teach that the reagent layer be any of the claimed reagent layer compositions.

However, MAO teaches a transition metal complex which can be used as a redox mediator (abstract). The complex contains a transition metal (inorganic) as well as a counter ion such as a chloride (making it a salt compound) [0028-0035].

Further, SAY teaches that quinhydrone can be used as a redox species in an electrochemical analyte sensor (col. 19, lines 13-26).

The motivation for using a transition metal complex like that of MAO as the redox mediator is the teaching that such mediators are known to have high stability in many different conditions, as well as a high selectivity for target analyte [0006]. Further, while SAY teaches that partially oxidized quinhydrones are taught to be disadvantageous due to interfering protein interactions, the prior art does teach that other quinones (possibly unoxidized quinhydrones) can be advantageously used due to the fact that they are less reactive with interfering protein functional groups [0144]. In the present case, the prior art teaches all the claimed reagent compositions, so the use of any single one of them would have been obvious. The combination of the two is likely to be successful because of their common use in the art and well understood properties. Therefore, at the time of the invention, it would have been *prima facie* obvious to one of ordinary skill in the art to combine the reagents of MAO and SAY and use them as the reagent layer in DAVIES because the combination of well known elements into one invention that avoids the prior art does not necessarily yield a novel invention.

18. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over DAVIES in view of BOON et al. (*Nat. Biotech.*, Vol. 18, 09/2000, 1096-1100), from here on referred to as BOON.

Concerning Claim 33, DAVIES teaches all the limitations of claim 7.

DAVIES does not expressly teach the claimed composition for the reagent layer.

However, BOON teaches a method of detecting mutations in DNA via DNA-modified electrodes (title), said electrodes comprising immobilized single-stranded oligonucleotides which are then hybridized with unmodified compliments of themselves (pg. 1097, "DNA-modified films for electrocatalysis"). This hybridization step necessitates the presence of three specific components and is well known in the art:

- A primer to signal where the hybridization should begin
- A DNA polymerase, for catalyzing the hybridization
- Deoxyribonucleotide triphosphates (dNTPs) as the building blocks used by the DNA polymerase for the hybridization

In the present case, the choice of what kind of reagent would be used in a sensor is a matter of design choice. There are a finite number of detection techniques which then dictate the type of reagent best suited for the technique. For example, should the device be designed to detect salts or gases, a conventional reagent such as potassium ferricyanide is probably more suitable. However, if the target is mutated DNA sequence, a biosensor based on the principles of a polymerase chain reaction (PCR) like that of BOON is highly advantageous in the study and treatment of genetic disease and may yield more helpful results (BOON, pg. 1096, paragraph 1). The substitution of a PCR-like sensor like in BOON for the ferrocene mediator in DAVIES is unlikely to produce unexpected results, since both reagent techniques are well known the art and therefore the behavior of each reagent is well known and could be predicted. At the time of the invention, therefore, it would have been *prima facie* obvious to one of ordinary skill in the art to substitute a PCR-like probe with the reagents in BOON for the reagent of DAVIES as doing so would lend the device of DAVIES increased functionality, such as use within the fields of disease detection and treatment (BOON, pg. 1096, paragraph 1).

19. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over DAVIES in view of BOON and further in view of MAO and further in view of SAY.

Concerning Claim 35, DAVIES teaches all the limitations of claim 7.

DAVIES does not expressly teach that the reagent layer be any of the claimed reagent layer compositions.

However, MAO teaches a transition metal complex which can be used as a redox mediator (abstract). The complex contains a transition metal (inorganic) as well as a counter ion such as a chloride (making it a salt compound) [0028-0035].

Further, SAY teaches that quinhydrone can be used as a redox species in an electrochemical analyte sensor (col. 19, lines 13-26).

Further, BOON teaches a method of detecting mutations in DNA via DNA-modified electrodes (title), said electrodes comprising immobilized single-stranded oligonucleotides which are then hybridized with unmodified compliments of themselves (pg. 1097, "DNA-modified films for electrocatalysis"). This hybridization step necessitates the presence of three specific components and is well known in the art:

- A primer to signal where the hybridization should begin
- A DNA polymerase, for catalyzing the hybridization
- Deoxyribonucleotide triphosphates (dNTPs) as the building blocks used by the DNA polymerase for the hybridization

The motivation for using a transition metal complex like that of MAO as the redox mediator is the teaching that such mediators are known to have high stability in many different conditions, as well as a high selectivity for target analyte [0006]. Further, while SAY teaches that partially oxidized quinhydrones are taught to be disadvantageous due to interfering protein interactions, the prior art does teach that other quinones (possibly unoxidized quinhydrones) can be advantageously used to their being less reactive with interfering protein functional groups [0144]. However, if the target is mutated DNA sequence, a biosensor based on the principles of a polymerase chain reaction (PCR) like that of BOON is highly advantageous in the study and treatment of genetic disease and may yield more helpful results (BOON, pg. 1096, paragraph 1). In the present case, the prior art teaches all the claimed reagent compositions, so the use of any single one of them would have been obvious. The combination of all these mediators is likely to be successful because of their common use in the art and well understood properties. Therefore, at the time of the invention, it would have been *prima facie* obvious to one of ordinary skill in the art to combine the reagents of BOON, MAO and SAY and use them as the reagent layer in DAVIES to facilitate the creation of a sensor with multiple simultaneous functionalities.

20. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over DAVIES in view of MIKKELSEN et al. (US 5,312,527), from here on referred to as MIKKELSEN.

Concerning Claim 36, DAVIES teaches all the limitations of claim 7.

DAVIES does not expressly teach that the reagent layer be a nucleic acid probe.

However, MIKKELSEN teaches a sensor comprising an immobilized polynucleotide probe.

The motivation for using the polynucleotide probe of MIKKELSEN in the device of DAVIES is the new functionality of virus detection (col. 4, lines 15-17), comprising a probe which is both highly sensitive and specific (col. 3, line 2) as well as reusable (col. 3, line 3). At the time of the invention, therefore, it would have been *prima facie* obvious to one of ordinary skill in the art to substitute a nucleic acid probe with the reagents in MIKKELSEN for the reagent of DAVIES as doing so is simply a matter of experimental design choice or intended use.

21. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over DAVIES in view of SAY.

Concerning Claim 40, DAVIES teaches all the limitations of claim 38.

DAVIES does not expressly teach that the biosensor have a wireless unit like Bluetooth.

However, SAY teaches an analyte monitoring device (title) comprising a transmitter (claim 11) wherein the transmitter is configured to wirelessly transmit detected analyte concentrations via a Bluetooth communication protocol (claim 13).

The motivation for using wireless transmission of target analyte detection signals is the elimination of the coupled biosensor/detector. The biosensor would not need to be handled after application of the sample which would save time and allow for more efficient sample collection protocols. Given the already significant signal collection and display features of DAVIES, the implementation of wireless communication into the device would be unlikely to yield unpredictable results or adversely affect the device. Therefore, at the time of the invention, it would have been *prima facie* obvious to one of ordinary skill in the art to provide the wireless, Bluetooth feature of SAY with the device of DAVIES to facilitate shorter sample detection times and ease of use.

22. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over DAVIES in view of CHARLTON et al. (US 5,759,364), from here on referred to as CHARLTON.

Concerning Claim 41, DAVIES teaches all the limitations of claim 1.

DAVIES does not expressly teach the biosensor also contain a desiccant.

However, CHARLTON teaches an electrochemical biosensor (title) which uses a desiccant to keep the sensor dry (col. 7, lines 37-38).

The motivation for using a desiccant like in CHARLTON would be, as mentioned above, to keep the internal components of the biosensor dry. A dry environment is advantageous, especially in storage, since a humid environment could lead to corrosion of the electrodes, causing the sensor to lose functionality. Therefore, at the time of the invention, it would have been *prima facie* obvious to one of ordinary skill in the art to use a desiccant like in CHARLTON in the sensor of DAVIES in order to prevent corrosion of the electrodes by a humid environment.

23. Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over DAVIES in view of HOAGLAND et al. (US 5,264,058), from here on referred to as HOAGLAND.

Concerning Claim 59, DAVIES teaches all the limitations of claim 2.

DAVIES does not expressly teach that the biosensor have a fixing tool attached to hold the folded substrate together.

However, HOAGLAND teaches a method of bonding of plastic and glass, in which increased pressure and temperature lead to bonding of the two materials (abstract). Further, HOAGLAND teaches that a clamp (fixing tool) is used to avoid wrinkling of the individual plastic layers (col. 3, lines 50-52).

In the present case, HOAGLAND can be considered analogous prior art because it teaches characteristics of plastic layer fixing. The motivation for providing a fixing tool in the device of DAVIES would be for more uniform biosensor creation, ensuring that the internal dimensions and therefore conditions of each biosensor are the same. Inconsistent formation of these sample chambers from biosensor to biosensor could lead to some sample chambers developing strange fluid flow characteristics, possibly interfering with capillary fill/flow mechanics or producing gas bubbles causing inconsistent flow patterns and possibly variable analyte detecting effectiveness. Therefore, at the time of the invention, it would have been *prima facie* obvious to one of ordinary skill in the art to use a fixing tool in the device of DAVIES so as to facilitate uniform mass production of the prior art biosensor.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT KASTEN whose telephone number is (571)270-7598. The examiner can normally be reached on Mon-Thurs, 8am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Sines can be reached on 571-272-1263. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/R. K./
Examiner, Art Unit 1795

/Brian J. Sines/

Supervisory Patent Examiner, Art Unit 1795